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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|---------------------|------------------|
| 10/015,391 | 12/12/2001 | Kevin P. Baker | GNE.2830P1C59 | 8886 |
| 35489 | 7590 | 08/10/2005 | | |
| HELLER EHRMAN LLP | | | EXAMINER | |
| 275 MIDDLEFIELD ROAD | | | STANLEY, STEVEN H | |
| MENLO PARK, CA 94025-3506 | | | | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1649 | |

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/015,391 | BAKER ET AL. |
| | Examiner | Art Unit |
| | Steven H. Standley | 1646 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 May 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 33,38-40 and 44-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 33,38-40, 44-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 5/27/05 has been received and entered in full.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

3. The Objection to the Oath/Declaration as set forth at pp. 2 ¶5 in the previous Office Action (24 June 2004) is hereby withdrawn due to applicant's amendment of 5/27/05.
4. The objection to claim 48 for typos is withdrawn because the applicant's arguments are persuasive.
5. The Rejection of claims 48-53 under 35 USC § 102(b) as anticipated by Bonaldo et al is withdrawn due to applicant's arguments.

Maintained Objections And/Or Rejections

Priority Determination

6. Applicant thanks the previous examiner for granting the priority of the instant application the date of the provisional application 60/141037, filed 6/23/1999. This examiner can find no record of the previous examiner granting priority to the provisional application filed 6/23/1999. Furthermore, the rejection of claims 33, 38-40, and 44-53

under 35 USC 101 stands. Therefore priority is maintained to be the date of the instant application, which is 9/04/01.

7. The objection of claim 48 for the use of the phrase "a complement thereof" is maintained. Applicant's arguments have been fully considered and found not to be persuasive. Applicant states on page 6 of the remarks dated 5/27/05 that "Applicants are simply claiming a fragment of the nucleic acid sequence that is at least 50 nucleotides long...or a complement thereof." The examiner asserts that "a complement thereof," does not indicate that the fragment is fully complementary to the 50 base pair fragment recited. It is suggested that "a complement thereof" be changed to "a fragment fully complementary to the 50 base pair fragment thereof," to obviate the objection.

Claim Rejections - 35 USC § 101

and

Claim Rejections - 35 USC § 112

8. Claims 33, 38-40, and 44-53 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well-asserted utility or a well established utility for the reasons as set forth at pp. 2-15 ¶6-13 in the previous Office Actions (6/24/04 and 3/22/05).

9. Claims 33, 38-40, and 44-53 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well-

asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the reasons as set forth at pp. 15 ¶14 in the previous Office Actions (6/24/04 and 3/22/05).

Applicant traversed the rejections in the Remarks dated 5/27/05 on the following grounds: "Applicants have clearly shown that the nucleic acid sequence of SEQ ID NO: 276 is amplified in a well-established and quantitative assay [page 11, top]," and that "the nucleic acids encoding PRO1317 had a [delta]C_t value of .1.0, which is more than a two-fold increase [page 14 bottom]," and "Applicants respectfully submit that the gene amplification data shown in the present application clearly demonstrates that the nucleic acid of SEQ ID NO: 276 is amplified in at least 7 primary lung tumors [page 21, top]."

The examiner respectfully directs applicant to the fact that gene amplification in lung tissue (via aneuploidy) occurs in non-cancerous tissue as well. The art recognizes that lung epithelium is at risk for cellular damage due to direct exposure to environmental pollutants and carcinogens, which result in aneuploidy *before* the epithelial cells turn cancerous. See Hittelman (2001, Ann. N. Y. Acad. Sci. 952:1-12), who teach that damaged, *pre-cancerous* lung epithelium is often aneuploid. See especially p. 4, Figure 4. Similarly, aneuploidy was found in morphologically normal colon tissue (Fleischhacker et al., Modern Path., 8:360, 1995; e.g., p. 360, col. 2). Because aneuploid DNA can be found in normal tissue, detection of increased DNA copy number does not necessarily mean those cells containing the DNA are cancerous. The gene amplification assay disclosed in the instant specification does not provide a comparison between the lung or colon tumor samples and normal lung or colon

epithelium control, and thus it is not clear that PRO1317 is amplified in cancerous lung or colon epithelium more than in damaged (non-cancerous) lung or colon epithelium. Thus, one skilled in the art would not conclude that PRO1317 is a diagnostic probe for lung or colon cancer. Furthermore, the information given in Table 8 was generated using PCR primers that measured amplification of the coding region of SEQ ID NO: 276. However, the claims are broadly drawn to variants of SEQ ID NO:276, including fragments and degenerate variants which have substitutions relative to SEQ ID NO: 276. One skilled in the art would expect that such variant sequences would lose their specificity as probes for the target sequence. Therefore, even if Applicant were to establish that the gene amplification assay provides utility and enablement for the coding region of SEQ ID NO: 276, the utility and enablement would not convey to the claimed variants.

10. The rejection claims **48-53** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed 5/27/05 have been fully considered but they are not persuasive for reasons made of record in the previous action of 6/24/04 and 3/22/05.

11. The rejection of claims **48-53** under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicant's arguments filed 5/27/05 have been fully considered but they are not persuasive for reasons made of record in the previous action of 6/24/04 and 3/22/05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims **33, 39-40, and 44-53** are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,764,677 B1 (20 July 2004; with priority to 14 June, 1999) Sharpe et al.

US '677 teaches a nucleic acid which shares 100% homology with SEQ ID NO: 276 for 2283 bp and therefore is "a complement of" SEQ ID NO: 282 thus meeting the limitations of claims 48-53 (SEQ ID NO: 18 therein; see Appendix A, result 1 and result 2). Sharpe et al. also teach "the full-length coding sequence" of SEQ ID NO: 276, thus meeting the limitations of claims 33 and 39-40 (see Appendix B which indicates Sharpe

et al discloses 100% of the coding region of SEQ ID NO: 276). Expression vectors and host cells are recited in the abstract of Sharpe et al., meeting the limitations of claims 44-46. Column 67 discloses *E. coli* as a host cell, meeting the limitations of claim 47.

13. Claim 48 is rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene (1991).

Stratagene et al disclose a random primer kit that contains oligonucleotides that are "a complement thereof" of SEQ ID NO: 276.

Summary

14. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
8/04/05



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